

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 22-729V

JEFFREY SCOTT CURRY,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

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Chief Special Master Corcoran

Filed: April 28, 2025

Richard Underwood, Harris/Shelton, PLLC, Memphis, TN, for Petitioner.

Emily Hanson, U.S. Dep’t of Justice, Washington, DC, for Respondent.

DECISION ON REMAND¹

On June 30, 2022, Jeffrey Scott Curry filed a petition for compensation under the National Vaccine Injury Compensation Program (the “Vaccine Program”).² Petition (ECF No. 1) (“Pet.”). Petitioner alleges that he experienced transverse myelitis (“TM”) due to a Tetanus-diphtheria-acellular pertussis (“Tdap”) vaccine he received on July 3, 2019. Pet. at 1.

After a complete review of the record, I denied entitlement on November 5, 2024. *See* Entitlement Decision (ECF No. 37) (“Decision”). On December 4, 2024, Petitioner filed a Motion for Review. (ECF No. 38). The motion was granted, and I have been ordered on remand to reevaluate Petitioner’s expert witness opinion and surrounding evidence in light of a factual error

¹ Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its present form. *Id.*

² The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-10–34 (2012)) (hereinafter “Vaccine Act” or “the Act”). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

contained in the original decision. Remand Order, dated Jan. 21, 2025 (ECF No. 42) (“Remand Order”).

Consistent with the Remand Order, I withdrew my original Decision and instructed the parties to brief certain issues. Order on Remand, dated Jan. 29, 2025 (ECF No. 43). They have now done so. Petitioner’s Brief, dated Mar. 14, 2025 (ECF No. 45) (“Remand Br.”); Responsive Brief, dated Apr. 14, 2025 (ECF No. 46) (“Responsive Br.”). Having reviewed the parties’ briefs, I reach the same conclusion as before, and find that Petitioner’s TM onset did not occur within a medically acceptable timeframe, measured from the date of vaccination.

I. Factual Background

Relevant History and Vaccination Event

Petitioner received the Tdap vaccine at issue³ on July 3, 2019, when he was 57 years old, during an annual exam at the office of his primary care provider (“PCP”). Ex. 4 at 7–11. The physical exam performed at this time yielded unremarkable results, and Petitioner expressed no specific health concerns at this time. *Id.*

There is no record evidence of any immediate post-vaccination complaints. Petitioner, however, argues in his briefing that a prostate exam performed at this exam was “extremely painful,” and that he felt extremely sore from it thereafter. Remand Br. at 1. Yet Petitioner’s affidavit specifically states *not* that he immediately experienced post-exam soreness he attributed to the prostate exam, but that within an hour of vaccination, he “began to notice that my legs began to feel very achy and stiff,” and that this feeling continued into July 4th (which is also identified as “the day [he] began experiencing trouble urinating”). Curry Affidavit, dated Oct. 10, 2022 (ECF No. 15) (“Curry Aff.”), at 1, ¶¶ 2–3. This affidavit makes no mention of prostate issues (although this does not mean that the symptoms Petitioner initially experienced could not be attributed to such concerns).

Post-Vaccination Symptoms and First Hospitalization

On July 5, 2019—only two days after the aforementioned PCP visit—Petitioner went to an urgent care facility for treatment of urinary retention that he reported had begun two days earlier (meaning on the day of his vaccination). Ex. 5 at 6 (“Patient comes in today for a Urinary retention”). He also informed treaters at this time, however, that he had received a prostate exam at his PCP appointment on July 3rd, and that the exam was “very tender and painful.” *Id.* A urine culture was negative for infection, with results consistent with contamination of the sample. *Id.* at

³ The record also shows Petitioner received the pneumococcal vaccine at this time as well, but Petitioner does not allege it to also have been causal of his TM.

10. Petitioner was prescribed an antibiotic and was discharged with no clear diagnosis proposed beyond “retention of urine, unspecified.” *Id.* at 9.

The evening of the very next day (July 6, 2019), Mr. Curry took himself to a hospital emergency room, complaining of hypotension and difficulty walking since that same morning. Ex. 6 at 27. He informed treaters of his PCP visit on July 3rd, and of the prostate exam he had received at the time, plus the resulting worsening issues he was experiencing with urine retention, pain, and leg weakness (although he also identified onset as four—rather than three—days before). *Id.*

Petitioner was subsequently admitted to the hospital, with emergency treaters proposing initial diagnoses of prostatitis, urinary retention, near syncope, and hypotension. Ex. 6 at 33. A brain CT scan revealed generalized atrophy, a possible arachnoid cyst in the posterior fossa, and white matter changes suggestive of chronic microvascular ischemic disease. *Id.* at 32. And an abdominal/pelvic scan revealed a distended bladder with urine, a normal size prostate, degenerative changes in the spine, and arteriosclerosis. *Id.* at 127–28. Petitioner improved after receipt of additional antibiotics and fluids, and he was discharged on July 7, 2019, after being deemed to have returned to baseline. *Id.* at 24. The discharging records set forth the treater view that Mr. Curry “developed prostatitis, then developed hypotension,” with the latter resulting in his “generalized weakness.” *Id.* at 24.

Second Hospitalization and TM Diagnosis

Three days later, on July 10, 2019, Petitioner returned to the emergency room, now reporting that he had awoken that morning to weak legs plus pain in his lower back and abdomen. Ex. 6 at 275. On exam, Petitioner displayed “profound weakness” in his legs, and was unable to hold them up. *Id.* at 277. An MRI of his thoracic and lumbar spine revealed a non-enhancing patchy signal abnormality within the distal spinal cord, leading the radiologist to conclude Petitioner was likely experiencing TM or some form of benign neoplasm. *Id.* at 261. And cerebrospinal fluid testing indicated elevated protein and white blood cell levels as well. *Id.* at 515, 517. Petitioner was accordingly admitted a second time to the hospital, where he began a course of intravenous steroids and antibiotics. *Id.* at 269–70.

While hospitalized, Petitioner saw a number of specialists and underwent scans and testing, all in an effort to identify an etiologic explanation for his presentation. The first such neurologic consultation occurred on July 11, 2019, and at this time, Mr. Curry informed treaters that his July 3rd prostate exam had been painful, resulting in “difficulty walking the rest of the day.” Ex. 6 at 263. Those sensations persisted into July 4, 2019, although Petitioner was still able to ambulate. *Id.* at 264. Based on his overall presentation, the neurologist proposed that Petitioner might be experiencing myelitis, rejecting the possibility of a peripheral neuropathy, and suggested that additional lab work be performed to look at possible “vascular etiologies.” *Id.* at 264, 266.

A second neurologic consult (this time with a neurosurgeon) occurred on July 12th. It was again reported that Petitioner’s symptoms had arisen in connection with a July 3rd prostate exam. Ex. 6 at 259. After an inconclusive brain MRI, the treater opined that Petitioner had experienced “Transverse Myelitis of conus of uncertain etiology,” adding that there was no discrete mass nor surgical indication. *Id.* at 322. In addition, Petitioner now encountered the medical professional who is his expert in this case—neurologist Shiva Shankar Natarajan, M.D.—on July 13, 2019. *See* Ex. 6 Part I (ECF No. 1-8) at 319. (I have not been able to identify any records from this timeframe in which Dr. Natarajan discussed Petitioner’s earlier proposed prostatitis or its possible relationship to TM—and Petitioner has identified none either).

At this time, Petitioner began inpatient occupational therapy, plus more intravenous and oral medications. Ex. 6 at 302, 722. A second MRI of his thoracic and lumbar spine displayed worsening signal abnormality of the lower thoracic cord deemed characteristic of worsening myelitis, and Petitioner was started on a five-day course of IVIG.⁴ *Id.* at 297, 505. Petitioner remained weak thereafter despite the IVIG treatment, and he was discharged to inpatient rehabilitation on July 22, 2019, with a differential diagnosis proposing TM as “likely.” *Id.* at 267, 287.

Petitioner’s rehab continued through mid-August 2019. Ex. 8 at 254–314. During this period, he again informed treaters that he had experienced pain in the wake of the prostate exam performed during his July 3rd PCP visit, resulting in significant lower extremity pain that same night. Ex. 3 at 46. Another MRI (this time of Petitioner’s thoracic spine) performed in late July revealed a normal thoracic cord with normal signal intensity. Ex. 2 at 222. By the time of his discharge from in-patient rehab, he could ambulate with the assistance of a walker. *Id.* at 207–08. Petitioner continued to receive outpatient physical and occupational therapy treatments for the next seven months, however, showing improvement throughout. Ex. 8 at 687–1080, 1819.

In September 2019, Mr. Curry had a post-hospitalization visit with Dr. Natarajan. Ex. 7 at 44–46. Dr. Natarajan noted Petitioner’s existing TM diagnosis and ongoing weakness (despite his success in ambulating). *Id.*

Treatment in 2020 and Beyond

Petitioner has continued to obtain treatment for sequelae from his TM, although the medical records relevant to these events and occurrences shed little light on causation. He saw Dr. Natarajan several times in the first half of 2020, reporting some improvements but also lingering

⁴ “Intravenous Immunoglobulin (IVIG)” is defined as “[a] therap[y] prepared from a pool of immunoglobulins (antibodies) from the plasma of thousands of healthy donors. Immunoglobulins are made by the immune system of healthy people for the purpose of fighting infections...IVIG/SCIG work in different ways to prevent the body from attacking itself and to decrease several types of inflammation in the body.” *IVIG*, <https://rheumatology.org/patients/intravenous-immunoglobulin-ivig> (last visited Apr. 28, 2025).

sequelae like leg pain and foot tingling. Ex. 7 at 36–38 (February 5, 2020 visit), 32–35 (May 2020 visit). He experienced another hospitalization in late May 2020 for an unrelated condition (a blood clot in his left femoral artery), and at that time the treating cardiologist memorialized Petitioner’s daughter’s report of his alleged prior vaccine-caused TM. Ex. 6 at 1155, 1168. Other treaters noted, however, that Petitioner’s TM had no identified etiology. *See, e.g.*, Ex. 6 at 1162–64 (May 2020 neurology consult). Petitioner thereafter continued to inform treaters of his purported vaccine-caused adverse event. *See, e.g.*, Ex. 15 at 2, 34–35.

On December 13, 2023 (and hence during the pendency of this matter), Mr. Curry followed up again with Dr. Natarajan. Ex. 5 at 1. The “History of Present Illness” section of the record for this visit contains (in relevant part), the following narrative:

“There was some confusion about his presentation to the hospital. He says that he had his shot on the 3rd and the same day he had a prostate per rectal exam which was extremely painful. Subsequently, he started noticing painful urination and decreased drips of urination. He did not have any retention...On the 7th he started noticing pain in his legs...There was no residual urine. However, on the 10th he started noticing gait problems...and we subsequently diagnosed him to have [TM].”

Id. No other records bearing on causation have been filed in this matter.

II. Expert Opinions

A. *Petitioner’s Expert – Dr. Shiva Natarajan*

Dr. Natarajan was one of Petitioner’s early neurologic treaters, and he has offered two written expert reports in support of Petitioner’s claim. Report, dated June 30, 2023 (ECF No. 24-1) (“First Natarajan Rep.”); Report, dated Dec. 5, 2023 (ECF No. 27-1) (“Second Natarajan Rep.”). Dr. Natarajan proposes that it is more likely than not that the administration of the Tdap vaccine was causally related to Petitioner’s TM, and he deems early symptoms to reflect distinguishable prostate concerns. First Natarajan Rep. at 1.

Dr. Natarajan is a neurologist and practicing physician at Memphis Neurology in Germantown, TN. Natarajan CV, filed on June 30, 2023, as Ex. A (ECF No. 24-2) (“Natarajan CV”). He received his B.S. in Biology from Maulana Azad College in Calcutta, India. Natarajan CV at 1. He went on to receive his medical degree from Nilratan Sircar Medical College, where he also completed a post-graduate rotating internship. *Id.* at 2. Dr. Natarajan underwent residency and fellowship training at Lincoln Hospital in Bronx, NY, and the University of Pittsburgh. *Id.* He

is certified by the American Board of Psychiatry and Neurology. *Id.* He has conducted extensive clinical research and has received several awards in recognition of his expertise. *Id.* at 3–5.

First Report

Dr. Natarajan’s first report includes a summary of Petitioner’s medical history relevant to the claim. First Natarajan Rep. at 2–3. He maintained there was “no reasonable dispute” as to the accuracy of Petitioner’s TM diagnosis, stressing that it had been confirmed both by medical treater opinions set forth in the records, imaging, and exclusion of other diseases that could present with comparable nonspecific symptoms (*e.g.*, multiple sclerosis, lupus, paraneoplastic syndromes, etc.). *Id.* at 4.

Dr. Natarajan characterized TM as an “acutely evolving inflammatory demyelinating lesion of the spinal cord,” which can produce symptoms of “pain, discomfort, numbness bowel and bladder weakness, and clumsiness.” First Natarajan Rep. at 4. TM is more often than not monophasic, and can be confirmed by MRI imaging revealing “focal demyelination with inflammation and enhancement.”⁵ *Id.*

Petitioner’s TM, Dr. Natarajan maintained, was likely caused by the Tdap vaccine he received on July 3, 2019. First Natarajan Rep. at 4. In support, he referenced a single item of literature (although it was not filed in this matter). *Id.* (citing D. Tippet, *Relapsing Transverse Myelitis*, 41 *Neurology* 703–706 (1991)).⁶ TM has a likely immune-mediated pathogenesis, he added, making it likely that antibodies generated in response to the vaccine could cross-react with spinal cord myelin via the well-accepted mechanism of molecular mimicry. *Id.* at 5.

Dr. Natarajan also identified some case reports in which individuals incurred TM in a post-vaccination context. First Natarajan Rep. at 5 (citing R. Riel-Romero, *Acute Transverse Myelitis in a 7-Month-old Boy After Diphtheria-Tetanus-Pertussis Immunization*, 44 *Spinal Cord* 688, 688–91 (2006) (child with an upper respiratory infection two weeks prior to onset developed TM 17 days post-vaccination) (“Riel-Romero”); N. Agmon-Levin et al., *Transverse Myelitis and Vaccines: A Multi-Analysis*, 18 *Lupus* 1198–1204 (2009), filed as Ex. D (ECF No. 24-5) (“Agmon-Levin”). Neither of these articles, however, are particularly applicable to this context. Riel-Romero, for example, involves a pediatric case of TM rather than one in an adult, and the patient therein had a concurrent infection prior to onset. Agmon-Levin, by contrast, collects 37 case

⁵ “Enhancement” refers to “any method of exaggerating the visible difference between adjacent structures on imaging by administering contrast media/agents.” *Contrast enhancement*, <https://radiopaedia.org/articles/contrast-enhancement?lang=us> (last visited Apr. 28, 2025).

⁶ In fact, although Dr. Natarajan refers to several case reports and items of literature in his written expert report, Petitioner only filed a single case report.

reports involving post-vaccination TM, but only a few are specific to the Tdap vaccine—and the article has been criticized in prior decisions as proving little about causation.⁷

Dr. Natarajan also proposed that Petitioner’s TM began on July 6, 2019, when Petitioner reported “what I consider actual symptoms of myelitis for the first time.” First Natarajan Rep. at 4. It was on that day that Petitioner first presented at the emergency room complaining of difficulty walking that had just manifested that morning. *Id.* at 2. Dr. Natarajan acknowledged that the medical history (which, as noted above, includes numerous instances of Petitioner’s reporting of symptoms beginning the day of vaccination) was “complicated by prostate complaints,” but he deemed them insignificant and likely unrelated. *Id.* at 4. Instead, Dr. Natarajan reasoned, Petitioner was “simply trying to describe pain that he felt.” *Id.*

Second Report

In an effort to rebut Respondent’s expert report (discussed below), Dr. Natarajan offered a succinct second report. He emphasized his view that Petitioner’s immediate symptoms had to be attributable to prostatitis, and were thus distinguishable from the more TM-specific symptoms, like weakness, that Petitioner experienced four to five days post-vaccination. Second Natarajan Rep. at 2. The contentions about urinary retention, he maintained, lacked record support, as Petitioner was not diagnosed with this, nor did he receive a catheter, whereas he *had* been proposed to be experiencing prostatitis. *Id.* at 1. If urinary retention explained Petitioner’s condition, he should have experienced “an acute episode with potential organ damage” by July 6, 2019, when he went to the emergency room. *Id.* In the days following July 6, 2019, Petitioner’s TM-like symptoms more formally manifested—and in Dr. Natarajan’s view, this constituted his onset. *Id.*

Dr. Natarajan also sought to bulwark some of his other contentions. For example, he maintained that the mechanism of molecular mimicry was scientifically sound, and reasonably could be invoked as an explanatory mechanism for how a vaccine could cause TM. Second Natarajan Rep. at 1. TM’s rarity overall, moreover, meant that epidemiologic evidence had less value—while case reports were “important.” *Id.* at 1–2. And Respondent had no alternative explanation for Petitioner’s TM. *Id.* at 2. Given Dr. Natarajan’s view that “[t]here are no coincidences in medicine in the context of issues like this,” the absence of other explanations left only the Tdap vaccine as causal. *Id.*

⁷ As I noted in *Martinez v. Sec’y of Health & Hum. Servs.*, No. 16-738V, 2022 WL 4884923, at *29 (Fed. Cl. Spec. Mstr. Sept. 9, 2022), *mot. for review den’d*, 165 Fed. Cl. 76 (2023), “Agmon-Levin . . . has received criticism in the past for only identifying a small number of instances linking TM to vaccination—despite having reviewed *years* of published data in the search for such evidence. See *Pearson v. Sec’y of Health & Hum. Servs.*, No. 16-9V, 2019 WL 3852633, at *14 (Fed. Cl. Spec. Mstr. July 31, 2019) (giving limited weight to Agmon-Levin in a case alleging that flu vaccine caused TM, since Agmon-Levin referenced only two post-flu vaccine TM cases—based on a review of 39 *years* of published case reports) (emphasis in original).”

B. *Respondent's Expert – Dr. Marcelo Matiello*

Dr. Matiello (like Dr. Natarajan, a neurologist) prepared a written report as Respondent's expert. Report, dated Sept. 27, 2023, filed as Ex. A (ECF No. 26-1) ("Matiello Rep."). He opined that the onset of Petitioner's TM began on July 3, 2019, and he does not believe the Tdap vaccine is casually connected to Petitioner's TM. Matiello Rep. at 15.

Dr. Matiello is an Associate Professor of Neurology at Harvard Medical School and Board-certified Neurologist at Massachusetts General Hospital, where he serves as the associate director of the Neuromyelitis Optica Clinic and the Vice-Chair of Clinical Affairs. Matiello CV, dated Sep. 29, 2023, filed as Ex. B (ECF No. 26-20) ("Matiello CV"). He received his medical degree from the Federal University of Rio de Janeiro and completed his fellowships and residency at the Mayo Clinic, Yale New Haven Hospital and the Massachusetts General Hospital/Harvard Medical School. Matiello CV at 1–2. Throughout his career, Dr. Matiello has focused on clinical and biological susceptibility aspects of inflammatory and demyelinating diseases including Guillain-Barré syndrome, myasthenia gravis, optic neuritis, transverse myelitis (TM), multiple sclerosis, neuromyelitis optica spectrum disorders, and myelin oligodendrocyte glycoprotein antibody disease. Matiello Rep. 2. He has also authored numerous peer-reviewed papers and book chapters in the field of neurology and neuro-immunology. Matiello CV at 29–36.

Based on his own independent review of the medical records, Dr. Matiello concurred with the accuracy of Petitioner's TM diagnosis, noting "abnormal findings on physical exam, imaging of his spinal cord, and spinal fluid [testing results]." Matiello Rep. at 6. Petitioner's TM was most likely the idiopathic variety, meaning no clear etiologic explanation could be provided for it. *Id.* at 7. Testing received by Petitioner had not identified any possible autoantibodies that might explain the injury. *Id.* at 10.

TM initially presents with evidence of sensorimotor deficits in the extremities along with numbness, as well as pain. Matiello Rep. at 7. But it also often involves other autonomic nervous system⁸ dysfunction—which can manifest as bladder control/urinary retention issues. *See* S. Lopez Chiroboga & E.P. Flanagan, *Myelitis and Other Autoimmune Myelopathies*, 27 Continuum (Minneapolis Minn) 62, 63 (2021), filed as Ex. A-4 (ECF No. 26-5) (presenting features of myelitis include neurogenic bladder disfunction, usually in the form of urinary retention).

The medical records supported the conclusion, Dr. Matiello reasoned, that Petitioner's TM presented with his urinary retention complaints. Matiello Rep. at 8. He deemed urinary retention a

⁸ The autonomic nervous system is defined as "the portion of the nervous system concerned with regulation of the activity of cardiac muscle, smooth muscle, and glandular epithelium." *Autonomic Nervous System*, Dorland's Medical Dictionary Online, <https://www.dorlandonline.com/dorland/definition?id=111779> (last visited Apr. 28, 2025). In effect, it involves functions that are less directly controlled by a person.

“frequent feature” in cases of acute myelitis. *Id.*; D.M. Wingerchuk & B.G. Weinshenker, *Acute Disseminated Encephalomyelitis, Transverse Myelitis, and Neuromyelitis Optica*, 19 Continuum (Minneapolis, Minn.) 944, 951 (2013), filed as Ex. A-1 (ECF No. 26-2) (“Wingerchuk & Weinshenker”). It occurs because the harm to the spinal cord results in “disruption of the nervous system pathways innervating the lower urinary tract.” Matiello Rep. at 8. While bladder dysfunction often accompanies other TM symptoms, it can be the sole initial presenting symptom as well. *Id.* at 8–9; A. Gupta et al., *Urodynamic Profile in Acute Transverse Myelitis Patients: Its Correlation with Neurologic Outcome*, 8 J. Neurosci. Rural Pract. 44, 47 (2017), filed as Ex. A-10 (ECF No. 26-11) (“Gupta”) (“During the initial phase, the patients have the inability to void with urinary retention as a predominant complaint”); A. Hiraga et al., *Urinary Retention Can be the Sole Initial Manifestation of Acute Myelitis*, 251 J. Neurol. Sci. 110, 110–111 (2006), filed as Ex. A-9 (ECF No. 26-10) (“Hiraga”).

Here, Mr. Curry first sought urgent care for urinary retention issues two days post-vaccination, on July 5, 2019. Matiello Rep. at 8. But he reported to treaters a *vaccination-day* onset, and he continued to make the same representation at subsequent medical treater encounters. *Id.* at 3. And these complaints did not, in Dr. Matiello’s view, likely reflect the distinguishable problem of prostatitis or some sequela of Petitioner’s July 3rd prostate exam, as Dr. Natarajan proposed. Petitioner never received such a diagnosis in his subsequent efforts to seek medical assistance for his symptoms. Lab work (which included blood and urine testing) did not confirm the existence of an infection. And it was not likely that a rectal prostate exam would lead to such symptoms in any event. *Id.* at 9; J.A. Villanueva Herrero et al., *Rectal Exam*, StatPearls – NCBI Bookshelf (National Library of Medicine, National Institutes of Health), *available at* <https://www.ncbi.nlm.nih.gov/books/NBK537356/>, filed as Ex. A-12 (ECF No. 26-13).

Dr. Matiello maintained that an onset of one day was too short in time, measured from vaccination, to causally implicate the vaccine. The immune system “requires time to mount a response and develop memory cells capable of recognizing and responding to the targeted pathogen or its mimicked molecules.” Matiello Rep. at 14. Dr. Matiello proposed this process (which would include a lag and then logarithmic phase) could take days to weeks in total, and thus could not result in clinical symptoms the same day as vaccination. *Id.* at 14–15; C.A. Janeway Jr. et al., *Immunobiology: The Immune System in Health and Disease* (New York: Garland Science, 5th ed. 2001), filed as Ex. A-18 (ECF No. 26-19) (“Janeway”). As a result, the vaccine could not have caused Petitioner’s TM.

Besides onset, Dr. Matiello discussed causes for TM, rejecting Dr. Natarajan’s contention that it could be caused by a vaccine. TM, he explained, could be a monophasic demyelinating condition or a presenting aspect of a larger condition, like MS or a paraneoplastic syndrome. Matiello Rep. at 6. It has also been linked to other kinds of inflammatory disorders, such as lupus, or some specific infections (herpes zoster or Lyme disease, for example). *Id.*

Dr. Natarajan maintained that TM could be mediated by an autoimmune cross-reaction due to molecular mimicry between antigens in the Tdap vaccine and subcomponents of spinal cord myelin. Matiello Rep. at 9–10. But Dr. Matiello deemed the theory both “hypothetical and not specific to this case.” *Id.* at 10. He noted that no explanation had been provided for what the mimicking “cross-reactive epitopes” in the vaccine would be, or what the targets would be (something that he deemed more broadly unknown for TM). *Id.* And it was otherwise likely that the human immune system’s existing “checkpoints” would prevent such a process from occurring, especially in reaction to vaccination. *Id.* at 11.

Moreover, Dr. Natarajan relied on case reports, but Dr. Matiello characterized that kind of evidence as weakly supportive of causation. Matiello Rep. at 10. Agmon-Levin, he noted, only identified 43 instances of post-vaccination TM—based on review of *nearly 40 years* of data. *Id.* at 11 (citing Agmon-Levin at 2). Among the discussed incidents, six cases were excluded due to insufficient demographic and clinical data. Agmon-Levin at 2. By contrast, more reputable and reliable independent medical or scientific articles did not support a relationship between vaccination and comparable demyelinating diseases. Matiello Rep. at 12–13; *See, e.g.*, L.S. Walker & A.K. Abbas, *The Enemy Within: Keeping Self-Reactive T Cells at Bay in the Periphery*, 2 Nat. Rev. Immunol. 11–19 (2002), filed as Ex. A-14 (ECF No. 26-15) (discussing a case-control study that found no statistically-significant association between optic neuritis and several common vaccines); A. Langer-Gould, et al., *Vaccines and the Risk of Multiple Sclerosis and Other Central Nervous System Demyelinating Diseases*, 71 JAMA Neurol. 1506-13 (2014), filed as Ex. A-16 (ECF No. 26-17) (involving a case-control study of 780 cases of CNS acute demyelinating disease and finding no long-term association between vaccines and MS or any other CNS demyelinating disease).

III. Procedural History

This case was initiated in June 2022, and activated and assigned to me that same fall. After Respondent filed his Rule 4(c) Report disputing entitlement, the parties began the process of obtaining expert reports, with the final report filed in January 2024.

As noted above, I initially denied entitlement on November 5, 2024, and Petitioner thereafter sought review of that determination. The Motion for Review was granted, due to a factual error in my Decision. *See generally* Remand Order. Dr. Natarajan, one of Petitioner’s treaters and his sole expert witness, had been misidentified in my Decision as having only encountered Petitioner two months *after* his TM hospitalization, when in fact Dr. Natarajan had provided treatment to Petitioner at the time of his *second* July 2019 hospitalization. ECF No. 1-8 at 319. The Court deemed this error to undermine the credibility determinations made in dismissing Petitioner’s claim, since I had expressly given Dr. Natarajan’s opinion less weight due to his (purported) lack of immediate treater knowledge. Remand Order at 2–3.

In light of this error, the Court remanded the case, ordering me to reevaluate Dr. Natarajan's expert opinion in conjunction with the surrounding evidence. Remand Order at 1. The Court noted, however, that the Remand Order should not be read to suggest that the timing of Dr. Natarajan's initial contact with Petitioner *per se* required a different outcome. *Id.* at 2.

I subsequently struck my initial Decision, and instructed the parties to brief the issue (ECF No. 44), and they did so in March and April of 2025.

IV. Parties' Arguments

A. Petitioner

In his first brief (filed prior to the Motion for Review that occasions this Remand Decision), Petitioner addressed prongs one and two of *Althen v. Sec'y of Health and Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005), and how he maintained he had established that the Tdap vaccine caused his TM. *See generally* Petitioner's Brief, dated June 18, 2024 (ECF No. 34) ("Br."). To support the argument that TM is autoimmune in nature and can be triggered by vaccination, Petitioner points to the Agmon-Levin article. Br. at 4. Petitioner explains that molecular mimicry between infectious antigens and self-antigens is the most common causation mechanism. *Id.*; Agmon-Levin at 4. In his expert report, Dr. Natarajan expands on this theory, proposing that "[Petitioner's] immune system developed autoantibodies to the Tdap immunization that cross reacted with his own spinal cord myelin to cause an inflammatory demyelinating myelitis..." Br. at 4–5 (citing First Natarajan Rep. at 5).

In order to provide support for *Althen* prong three, Petitioner places great weight on the opinion of Dr. Natarajan, Petitioner's treating physician. Br. at 5. In his report, Dr. Natarajan states that "[Petitioner's] symptomology and clinical examinations are consistent with the vaccination being the cause of the injury and there is a proximate temporal relationship between the vaccine and the injury to the exclusion of other potential causes for his transverse myelitis." *Id.* at 6 (citing First Natarajan Rep. at 1). In clarifying his reasons for not including this opinion in Petitioner's medical records, Dr. Natarajan explains that his theory of causation made no difference from a clinical standpoint, and was irrelevant for purposes of treating the Petitioner. First Natarajan Rep. at 1.

Petitioner concludes his brief by addressing the temporal relationship between the Tdap vaccine and his injury. He purports that he did not experience true urine retention until July 11, 2019, when a catheter was placed. Br. at 6. Although Petitioner reported to Urgent Care on July 5, 2019, for painful urination, he was not at that time diagnosed with urine retention. *Id.* at 7 (citing Second Natarajan Rep. at 1). If Petitioner had experienced urine retention from July 5th to July 11th, "it would have resulted in an acute episode with potential organ damage." Second Natarajan

Rep. at 1. Thus, it is more likely that Petitioner's TM began several days later, on July 10, 2019—seven days after he received the vaccine. Br. at 7.

In his pre-appeal reply brief, Petitioner reiterates that he has established a proximate temporal relationship between the vaccine and his TM. Petitioner's Reply, dated July 11, 2024 (ECF No. 36) ("Reply") at 3. He notes that it is undisputed that the first manifestation of TM did not occur until after Petitioner received the vaccine. *Id.* He further argues that although a two to three days post-vaccination may be considered an early onset, it still falls within the onset range set forth in Agmon-Levin. *Id.* at 4. Therefore, it is reasonable to find that the onset of Petitioner's TM falls within the timeframe consistent with vaccine causation. *Id.*

B. *Respondent*

Respondent argues that Petitioner has not preponderantly demonstrated that the Tdap vaccine was the cause of his TM, and therefore requests that the case be dismissed. Respondent's Opposition, dated June 18, 2024 (ECF No. 35) ("Opp.") at 1. Petitioner has failed to meet *Althen* prong one because his molecular mimicry theory of causation lacks specificity in terms of this particular case. *Id.* at 14. In his expert report, Dr. Matiello explains that "the target for the autoimmune attack in patients with idiopathic TM is unknown," so even if Petitioner had presented evidence of sequence homology between the Tdap vaccine and spinal cord issue, such evidence would not prove causation. *Id.* at 15 (citing Matiello Rep. at 10). Furthermore, Respondent maintains that the case reports discussed in Agmon-Levin are unpersuasive, since "case reports. . . do not establish or prove a cause-and-effect relationship," and because over a thirty-nine-year period, Agmon-Levin's authors identified only *six* instances of TM occurring after the Tdap vaccine. *Id.* at 16 (citing Matiello Rep. at 10).

Respondent further contends that Petitioner has failed to meet *Althen* prong two, noting that Petitioner saw several physicians in addition to Dr. Natarajan over the course of his illness, yet none attributed his TM to the Tdap vaccine. Opp. at 20. In fact, where Petitioner's providers did document in a particular record a possible association between the vaccine and his TM, it appears to have been at Petitioner's suggestion. *Id.* Finally, Petitioner points out that Dr. Natarajan himself did not contemporaneously offer his suspicion that Petitioner's TM was caused by the Tdap vaccine in his treatment of Petitioner. *Id.* at 22.

Respondent concludes by opining that Petitioner has failed to establish a medically acceptable timeframe for onset under *Althen* prong three. Opp. at 22. Respondent acknowledges that the parties disagree as to the appropriate onset timeline for TM from which vaccine causation could be inferred—Dr. Natarajan opines that the onset of TM can occur within hours, while Dr. Matiello claims that the onset of TM can occur no sooner than four to seven days after a triggering incident. *Id.* (citing First Natarajan Rep. at 4; Matiello Rep. at 14). Dr. Matiello supports his

assertion with an excerpt from an immunology textbook, Janeway. Janeway explains that “there is a delay of 4-7 days before the initial adaptive immune response takes effect” to accommodate the process by which lymphocytes are deployed and replicated in response to an antigen. *Id.* at 23 (citing Janeway at 2, 11).

Respondent goes on to note that on July 5, 2019, Petitioner reported urinary retention “for the past two days”—meaning it likely began *the day of* vaccination. Opp. at 23; Ex. 5 at 6–9. On July 6, 2019, Petitioner reported that he had urinary retention, along with other symptoms, since July 3, 2019—the same day as his vaccination. Opp. at 24; Ex. 6 at 27. Dr. Matiello provided several medical articles that confirm the presence of urinary symptoms early in the course of TM, which led him to conclude that this was how Petitioner’s TM manifested. Opp. at 24–25 (citing Matiello Rep. at 15). The weight of the evidence therefore favors a finding that Petitioner’s TM began the day of vaccination. *Id.* at 26. Because an onset of TM within hours of vaccination is too rapid to infer causation, Petitioner cannot meet this third prong for causation. *Id.* at 27.

C. *Arguments on Remand*

As noted above, in the wake of the Remand Order, the parties have submitted additional briefing on a narrow issue: the lingering question of the meaning of Petitioner’s initial symptoms, whether they reflected a first manifestation of TM (neurogenic bladder) or unrelated prostatitis, and whether Dr. Natarajan’s treatment of Petitioner in July 2019 bears on that dispute.

1. Petitioner

Petitioner argues that the record and the testimony of both Drs. Natarajan and Matiello support a finding of entitlement. Consistent with the Remand Order, Petitioner notes that Dr. Natarajan treated Petitioner for the first time during his July 2019 hospital stay, giving him personal knowledge of the onset of Petitioner’s TM. Remand Br. at 3. Because Dr. Natarajan was an initial treating physician who diagnosed Petitioner’s TM, he was in the best position to evaluate his initial symptoms and their significance.

Petitioner seeks to differentiate symptoms relating to prostatitis from TM. To this end, he contends that the prostate exam he received on July 3, 2019, caused him excruciating pain, and he left feeling very sore and tender. Remand Br. at 1. He reported to urgent care two days later, on July 5, 2019, with urinary complaints. Remand Br. at 1; Ex. 5 at 6. But he did not have urinary *retention* at this time, as evidenced by his ability to urinate voluntarily for the purpose of lab testing. Remand Br. at 1–2. He thus argues that the “urinary retention” classification memorialized on this record was likely selected “for insurance purposes.” *Id.* at 1.

Petitioner presented to the ER the next day, on July 6, 2019, with a chief complaint of “inability to void” and “leg weakness.” Remand Br. at 2. Petitioner was admitted to the hospital, where he was diagnosed with prostatitis by Dr. Henry Stamps. *Id.*; Ex. 6 at 24. Even though the pain persisted, Petitioner was able to urinate on his own at this time. Remand Br. at 2. The next day, he felt much better and was “anxious to leave.” *Id.*; Ex. 6 at 21. Petitioner was discharged, and his records from that day indicate that his prostatitis resulted in hypotension, which led to generalized weakness. Remand Br. at 2; Ex. 6 at 24. The records also indicate that all of Petitioner’s urinary symptoms had completely improved after treatment for prostatitis. Remand Br. at 2; Ex. 6 at 22. Furthermore, a CT scan on July 6, 2019 revealed no evidence of TM. Remand Br. at 3; Ex. 6 at 22.

Petitioner notes that hypotension and prostatitis are not early signs of TM. Remand Br. at 3. Once he was treated for prostatitis, his symptoms subsided, and his strength returned. *Id.* It was not until July 10, 2019, ten days post-vaccination, that Petitioner was transported to the hospital by ambulance and diagnosed with TM after he exhibited an inability to move his legs. *Id.*

Petitioner further maintains (based on Dr. Natarajan’s expert report) that Petitioner could not have been suffering from urinary retention from July 6-10, 2019, because urinary retention for that length of time would have resulted in an acute episode with potential organ damage. Remand Br. at 3–4; Second Natarajan Rep. at 1. Petitioner otherwise argues that his initial urinary issues were not neurologic in nature. Remand Br. at 4. He had no neurological red flags prior to his July 10th visit, which is why neurology was not called. *Id.* Instead, his early symptoms (painful urination, difficulty urinating, etc.) were “classic” for prostatitis, and he was treated accordingly. *Id.* at 1–2, 4. And even if Petitioner were experiencing urinary retention, it would be consistent with bacterial prostatitis. *Id.* Thus, Petitioner argues that the prostatitis was a “red herring,” with his actual TM beginning days later. *Id.* at 5.

Petitioner has also contended that his urinary complaints included burning on urination, which is not a symptom of TM but which he “reported in writing three times” that he was experiencing. Remand Br. at 5 and Ex. J to same (ECF No. 45-10).⁹ The document upon which this contention is based, however, is a single, undated form (entitled “International Prostate Symptom Score”) which appears to be a questionnaire allowing a patient (here, likely Mr. Curry) to indicate the extent to which he is experiencing different symptoms. The document in question contains three instances in which the term “burning” is written. Ex. J. In addition, the document comes from a set of records produced by urologist Dr. William Van Bingham—who appears to have first seen Petitioner in August 2019, and thus after both his initial TM-related hospitalization

⁹ It is ordinarily the practice in Vaccine Program cases for Petitioners to number their exhibits, and not use letter references. But it is clear from the contents of Exhibit J that it merely reproduces a previously-filed Exhibit 11 (ECF No. 1-15) at 7.

and the alleged prostate-related complaints memorialized in the record from early July 2019). *See, e.g.*, Ex. 11 at 51 (progress noted dated August 7, 2019).¹⁰

2. Respondent

Respondent contends that Petitioner's onset of TM occurred within 24 hours of vaccination, based on contemporaneous records documenting the onset of urinary retention and leg weakness as early as the same day as vaccination. Responsive Br. at 9–12; Ex. 5 at 6–9 (July 5th urgent care record documenting onset of urinary retention two days prior); Ex. 6 at 27 (July 6th emergency room record documenting July 3rd physical and prostate exam, and Petitioner's report that "since the exam he has had issues with pain, urinary retention, and weakness in his legs").

To support his claim that he was suffering from prostatitis during his first hospitalization in early July 2019, Petitioner points to the fact that his symptoms improved after he received fluids and antibiotics. Responsive Br. at 9. Respondent acknowledges that Petitioner improved sufficiently for him to be discharged on July 7th, but highlights that his condition thereafter worsened. *Id.* Furthermore, Petitioner does not adequately distinguish between the symptoms he alleges are prostatitis and his TM symptoms. *Id.*

Although Petitioner received a diagnosis of prostatitis early on in his disease course, Respondent argues that objective findings in the medical records reveal the diagnosis's inaccuracy. Responsive Br. at 10. On July 5, 2019, Petitioner reported to urgent care with urinary retention. *Id.*; Ex. 5 at 6–9. On exam, Petitioner's prostate was normal and non-tender to palpitation. Ex. 5 at 8. The next day, Petitioner underwent an abdominal and pelvic CT, which showed a normal sized prostate. Ex. 6 at 127–28. These records undermine the conclusion that a prostate issue was the explanation for his symptoms. Responsive Br. at 10.

Furthermore, Petitioner's claim that he did not have urinary retention before his more obvious neurologic symptoms is contradicted by the record. Responsive Br. at 11. Petitioner reported urinary retention, and then was diagnosed with urinary retention on July 5th, and a July 6th CT scan confirmed the existence of bladder distention. *Id.*; Ex. 5 at 6; Ex. 6 at 127. Urinary retention does not necessarily mean that Petitioner was completely unable to urinate, moreover. Responsive Br. at 11. In an article cited by Dr. Natarajan, the clinical description of TM states that "virtually all patients have *some degree* of bladder dysfunction," and that autonomic symptoms characteristic of TM include "*difficulty* or inability to void." *Id.* (emphasis added), *citing* A. Kaplin,

¹⁰ There is also a record from Petitioner's July 7, 2019 discharge after his first hospitalization that provides generalized information about prostatitis, and the fact that it can result in "burning with urination." Ex. 6 (ECF No. 1-8) at 167. But this document is not specific to the Petitioner's complaints at the time.

et al., *Diagnosis and Management of Acute Myelopathies*, 11 NEUROLOGIST 2-18, 2 (2005) (filed as ECF No. 27-3) (“Kaplin”).

The 24-hour onset finding is also consistent with the medical literature provided to support Dr. Matiello’s opinion that urinary retention was the first symptom of Petitioner’s TM. Responsive Br. at 11 (*citing* Kaplin). By contrast, Dr. Natarajan did not offer sufficient evidence to support his contention that Petitioner’s urinary retention was better explained by prostatitis, and/or that total retention is necessary for the condition to reflect TM, or to exist at all. *Id.*

Respondent also argues that even though Dr. Natarajan did treat Petitioner in July 2019, my original observation that Dr. Natarajan lacked first-hand knowledge of Petitioner’s disease course from the date of vaccination to when he encountered Petitioner remained valid. Responsive Br. at 6. The record suggests that Dr. Natarajan first saw Petitioner on July 13, 2019—*eight days* after Petitioner’s initial presentation to urgent care on July 5, 2019. *Id.* Thus, Dr. Natarajan’s opinion about the nature of Petitioner’s initial symptoms was still not entitled to significant weight. *Id.* at 7. Dr. Natarajan was not present in the early days of Petitioner’s illness, and even when he began meeting with Petitioner, he did not take a history of Petitioner’s present illness or inquire about the onset of his symptoms. *Id.* Accordingly, the error as to the date of Dr. Natarajan’s first encounter with Petitioner does not, and should not, alter the conclusion that Petitioner’s TM began soon after vaccination. *Id.* In fact, even if Dr. Natarajan had begun treating Petitioner in the earliest days of his illness, voluminous record evidence is still supportive of an onset too close-in-time to vaccination to be medically acceptable. *Id.* at 9–10.

V. Applicable Legal Standards

A. Petitioner’s Overall Burden in Vaccine Program Cases

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a “Table Injury”—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a “Non-Table Injury”). See Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec’y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec’y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).¹¹ There is no Table injury for TM after receipt of any covered vaccine.

¹¹ Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec’y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec’y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff’d* 104 F. App’x. 712 (Fed. Cir. 2004); *see also Spooner v. Sec’y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

For both Table and Non-Table claims, Vaccine Program petitioners bear a “preponderance of the evidence” burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the “trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact’s existence.” *Moberly*, 592 F.3d at 1322 n.2; *see also* *Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec’y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was “not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury.” *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec’y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec’y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec’y of Health and Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005): “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury.”

Each *Althen* prong requires a different showing. Under *Althen* prong one, petitioners must provide a “reputable medical theory,” demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner’s theory must be based on a “sound and reliable medical or scientific explanation.” *Knudsen v. Sec’y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be “legally probable, not medically or scientifically certain.” *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec’y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed “not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act’s preponderant evidence standard.” *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245 (“[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one” (emphasis in original)).

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. See *Kalajdzic v. Sec'y of Health & Hum. Servs.*, No. 2023-1321, 2024 WL 3064398, at *2 (Fed. Cir. June 20, 2024) (arguments “for a less than preponderance standard” deemed “plainly inconsistent with our precedent” (citing *Moberly*, 592 F.3d at 1322)); *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); see also *Howard v. Sec'y of Health & Hum. Servs.*, 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) (“[t]he standard has been preponderance for nearly four decades”), *aff'd*, 2024 WL 2873301 (Fed. Cir. June 7, 2024) (unpublished). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* “addresses the petitioner’s overall burden of proving causation-in-fact under the Vaccine Act” by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner’s medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine “did cause” injury, the opinions and views of the injured party’s treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 (“medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a ‘logical sequence of cause and effect show[s] that the vaccination was the reason for the injury’”) (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that “[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court”); *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) (“there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted”). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians’ conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V,

2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a “proximate temporal relationship” between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase “medically-acceptable temporal relationship.” *Id.* A petitioner must offer “preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation.” *de Bazan v. Sec’y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one’s requirement). *Id.* at 1352; *Shapiro v. Sec’y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den’d after remand*, 105 Fed. Cl. 353 (2012), *aff’d mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec’y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. den’d* (Fed. Cl. Dec. 3, 2013), *aff’d*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Legal Standards Governing Factual Determinations

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider “all [] relevant medical and scientific evidence contained in the record,” including “any diagnosis, conclusion, medical judgment, or autopsy or coroner’s report which is contained in the record regarding the nature, causation, and aggravation of the petitioner’s illness, disability, injury, condition, or death,” as well as the “results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.” Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec’y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master’s discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, “[m]edical records, in general, warrant consideration as trustworthy evidence.” *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec’y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) (“[g]iven the inconsistencies between petitioner’s testimony and his contemporaneous medical records, the special master’s decision to rely on petitioner’s medical records was rational and consistent with applicable law”), *aff’d*, *Rickett v. Sec’y of Health & Hum. Servs.*, 468 F. App’x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those

professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) (“[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms”).

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also* *Murphy v. Sec'y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) (“[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.”)).

However, the Federal Circuit has also noted that there is no formal “presumption” that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) (“like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking”); *Lowrie*, 2005 WL 6117475, at *19 (“[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent”) (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be “consistent, clear, cogent, and compelling.” *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything

reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). Under *Daubert*, the factors for analyzing the reliability of testimony are:

- (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication;
- (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) (“uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted”). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g., Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be “based on the

credibility of the experts and the relative persuasiveness of their competing theories.” *Broekelschen v. Sec’y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert’s conclusion “connected to existing data only by the *ipse dixit* of the expert,” especially if “there is simply too great an analytical gap between the data and the opinion proffered.” *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec’y of Health & Hum. Servs.*, No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den’d*, 108 Fed. Cl. 743 (2013), *aff’d*, 540 F. App’x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert’s credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 (“[a]ssessments as to the reliability of expert testimony often turn on credibility determinations”); *see also Porter v. Sec’y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) (“this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act”).

D. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner’s case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec’y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) (“[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision”) (citation omitted); *see also Paterek v. Sec’y of Health & Hum. Servs.*, 527 F. App’x 875, 884 (Fed. Cir. 2013) (“[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered”).

E. *Resolution of Matter Without Hearing*

I am resolving Petitioner’s claim on the filed record. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec’y of Health & Hum. Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec’y of Health & Hum. Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec’y of Health*

& *Hum. Servs.*, 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec’y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

The failure to establish even one of the three *Althen* prongs in the context of a causation-in-fact claim is sufficient basis for a claim’s dismissal (and therefore the three prongs need not be *all* addressed in cases where a claimant clearly fails at least one). *Dobrydnev v. Sec’y of Health & Hum. Servs.*, 566 Fed. Appx. 976, 980 (Fed. Cir. 2014).¹² Upon remand, I once again determine that the primary deficiency in Petitioner’s claim is his inability to satisfy the third *Althen* prong. *Althen*, 418 F.3d at 1281. Petitioner has not preponderantly established that his TM developed within a medically-acceptable timeframe after he received the Tdap vaccine.

It is well understood in the Vaccine Program that the onset of an alleged vaccine injury is marked by the “first symptom or manifestation of onset.” *See* Section 16(a)(2). As the Federal Circuit makes clear in *Markovich v. Sec’y of Health & Hum. Servs.*, 477 F.3d 1353, 1357 (Fed. Cir. 2007), there is a difference between a “symptom” and “manifestation of onset”—but because of the Act’s use of the disjunctive “or,” *either* can constitute the start of a disease process (even though a symptom could be nonspecific, or hard to link to what was later viewed as a full disease). *Markovich*, 477 F.3d at 1357–59. As a result, the date of official diagnosis, and/or when treaters were *able* to reach a conclusion as to the proper diagnosis, does *not* mark the onset of an alleged vaccine injury. *Carson v. Sec’y of Health & Hum. Servs.*, 727 F.3d 1365, 1369 (Fed. Cir. 2013) (“it is the first symptom or manifestation of an alleged vaccine injury, not first date when diagnosis would be possible, that triggers the statute of limitations under § 300aa–16(a)(2).”). Nor is onset deemed the date an injured party *recognizes* the subsequent disease has begun, or even understands the symptom to be concerning. *See Markovich*, 477 F.3d at 1357 (“[a] symptom may be indicative of a variety of conditions or ailments, and *it may be difficult for lay persons to appreciate the medical significance of a symptom with regard to a particular injury*”) (emphasis added). Onset can predate the time when a disease could be accurately diagnosed. *Id.*¹³

The record in this case demonstrates that Petitioner reported onset of symptoms that could reasonably be understood to reflect TM as early as *the day of vaccination*. *See, e.g.*, Ex. 5 at 6 (urgent care record from July 5th documenting the onset of Petitioner’s urine retention as two days prior); Ex. 6 at 27 (“since the [prostate] exam, [Petitioner] has had issues with pain, urinary retention, and weakness in his legs”); Curry Aff. at 1, ¶¶ 2–3 (claiming Petitioner experienced leg

¹² Even if the Court determines on a subsequent appeal that Petitioner’s TM likely did begin in a medically acceptable timeframe, the first *Althen* prong would still be legitimately disputed in this case, and hence require resolution.

¹³ Although the injured child in *Markovich* was not diagnosed with a seizure disorder until August 2000, it was determined in that case that the onset of the disease dated back a month earlier, when the child suffered from an eye-blinking episode that was later determined to be the first symptom of her seizure disorder. *Markovich*, 477 F.3d at 1357, 1360.

aches and stiffness “[a]s quickly as one hour after receiving the Tdap vaccine,” and also maintaining those sensations persisted into the next day, along with “trouble urinating,” along with a sensation of “jerky legs”). Petitioner maintains these symptoms were merely the byproducts of prostatitis, and are thus distinguishable from his later-diagnosed TM. But as Respondent more persuasively has demonstrated, the record does not support this conclusion, for several reasons.

First, Respondent has clearly established that urinary and bladder issues *can* be presenting symptoms of TM. *See* Wingerchuk & Weinschenker at 951 (“[m]ost [TM] patients present with a combination of sensory, motor, and bladder or bowel-related symptoms...”) (emphasis added); Gupta at 46–47 (“[b]ladder dysfunction is an integral part in majority and could be the presenting symptom of transverse myelitis. . . . During the initial phase, the patients have the inability to void with urinary retention as a predominant complaint”); Hiraga at 111 (“urinary retention can be the sole initial manifestation of [acute myelitis]”). In addition, issues specific to urine retention need not be total, i.e. mere *difficulty* urinating can be proof of neurogenic bladder concerns that are a harbinger of TM. *See, e.g.*, Kaplin at 6 (“[a]utonomic [TM] symptoms consist variably of increased urinary urgency, bowel or bladder incontinence, *difficulty or inability* to void, incomplete evacuation, or bowel constipation”) (emphasis added).

Because of this, special masters have often deemed evidence of bladder-related complaints to reflect a potentially-presenting symptom of TM. *See, e.g., Le v. Sec’y of Health & Hum. Servs.*, No. 16-1078V, 2023 WL 3049203, at *34 (Fed. Cl. Spec. Mstr. Mar. 30, 2023) (petitioner’s bladder dysfunction was a medically-recognized symptom marking the onset of his TM); *R.P. v. Sec’y of Health and Hum. Servs.*, No. 13-591V, 2019 WL 98938, at *33 (Fed. Cl. Spec. Mstr. Feb. 4, 2019) (child’s urinary output was a symptom of pediatric TM). It does not matter that Petitioner was not—or could not be—*diagnosed* with TM until some time after his urinary symptoms developed, or that Petitioner mistook his initial symptoms to be the byproduct of a physical exam. For purposes of the Vaccine Act, the first symptom or manifestation of an injury is “the first event *objectively recognizable by the medical profession at large.*” *Markovich*, 477 F.3d at 1360 (emphasis added).

Because urinary issues are recognized as a precursor for TM, the onset of Petitioner’s illness in this case could reasonably be set as when he first complained of bladder-related issues, as opposed to when he was later diagnosed with TM. The medical history that later led to the diagnosis clearly involved the manifestation of *additional* symptoms and testing that corroborated their meaning. But for purposes of onset in this case, the record preponderantly supports the conclusion that the disease process had begun well before the date of diagnosis.

Second, Petitioner’s efforts to distinguish his earlier symptoms as attributable to unrelated prostatitis are unpersuasive. He specifically draws attention to the fact that he lacked *complete* urine retention, with Dr. Natarajan maintaining that such a degree of retention should have had acute and dangerous consequences had it existed. Second Natarajan Rep. at 1. Petitioner further

denies experiencing urine retention on July 5, 2019, noting that he was able to provide a urine sample at his initial visit to urgent care.

But as Respondent points out (and as is corroborated by several items of literature filed in this case) “urine retention” does not necessarily mean a *complete inability* to void for an extended period of time. Again—the record consistently identifies the existence of *retention concerns* (albeit without an initial determination of their basis). Thus, on July 5, 2019, “retention of urine, unspecified” was listed as part of Petitioner’s differential diagnosis, and on July 6, 2019, a CT scan confirmed that Petitioner’s bladder was distended. Ex. 5 at 9; Ex. 6 at 127–28. The fact of this retention as a concern is clear from the medical record.

In addition, and despite the fact that prostatitis remained in Petitioner’s diagnostic differential, it was never formally confirmed by subsequent testing. *See* Ex. 5 at 8 (Petitioner’s prostate was normal and nontender to palpitation on exam); Ex. 6 at 127–28 (pelvic CT showed a normal sized prostate). This evidence further undermines the contention that any urine retention concerns were attributable to prostate dysfunction. While prostatitis may well have been a reasonable suspicion of initial treaters (especially since Petitioner *reported* it as the cause of his complaints), the evolution of Petitioner’s symptoms and complaints later resulted in his TM diagnosis. And that later diagnosis (which is not disputed in this case) puts Petitioner’s initial complaints or personal suspicions in a different light.

Third, while my earlier entitlement decision erroneously stated that Dr. Natarajan did not encounter Petitioner into well after his July 2019 hospitalization, the fact that he *did* see Petitioner that July (rather than merely in post-hospitalization follow-up) does not make it more likely that prostatitis is the proper characterization for Petitioner’s initial symptoms. For one thing, the record suggests that Dr. Natarajan first saw Petitioner on July 13, 2019—*eight days* after Petitioner’s initial presentation to urgent care. By that time, Petitioner had already been admitted to the hospital, treated, discharged, and then re-admitted. Because Dr. Natarajan was not present in the earliest days of Petitioner’s illness, my original observation still has objective evidentiary support: Dr. Natarajan has not been established to have personal, directly-contemporaneous knowledge of the circumstances of Petitioner’s *onset*.

There is also the fact that records pertinent to Dr. Natarajan’s treatment of Petitioner while hospitalized (when he might have weighed in on the question of prostatitis vs. neurogenic bladder consistent with TM) do not add ballast to the conclusion that Petitioner’s early symptoms were related to prostatitis only. I cannot identify any records from Dr. Natarajan’s initial treatment of Petitioner in which he discussed prostatitis (and Petitioner—who bears the burden of proof in this case—has identified none). Otherwise, Dr. Natarajan’s opinion seems to conflate when sufficient evidence existed to *diagnose* Petitioner with TM, based on more obvious evidence of TM, versus when his first possibly-related TM symptoms manifested. *See, e.g.*, First Natarajan Rep. at 4; Second Natarajan Rep. at 2. The Program looks to the latter in determining onset. *Markovich*, 477 F.3d at 1357.

Undoubtedly, treater opinions are entitled to some weight in resolving entitlement. Section 13(b)(1); *Synder v. Sec’y of Health & Hum. Servs.*, 86 Fed. Cl. at 746 n.67 (2009). But special masters are never obliged to accept a treater opinion on its face. *J.S. v. Sec’y of Health & Hum. Servs.*, No. 16-1083V, 2022 WL 20213038, at *22 (Fed. Cl. Spec. Mstr. July 15, 2022) (recognizing the Program’s oft-noted admonition that treater views are never *per se* sacrosanct or dispositive). Here, I give less weight to Dr. Natarajan’s characterization of Petitioner’s initial presenting symptoms—both because (a) credible and reliable independent scientific and medical literature clearly stands for the proposition that TM can present with bladder-related issues, and (b) it has not been shown that Dr. Natarajan possessed personal knowledge of Petitioner’s treatment in the approximately ten days between his vaccination and when it appears Dr. Natarajan did encounter Mr. Curry in the hospital.

The Remand Order also directs me to flesh out the distinction between “urinary retention” and “burning” as they relate to Petitioner’s TM diagnosis. Remand Order at 3 n.3. I agree that they are distinguishable concepts, and that a burning sensation associated with urination could be reflective of prostatitis (as an informational document that appears to have been provided to Petitioner at the end of his first hospitalization states. *See* Ex. 6 at 167). But Petitioner has identified only *one other treatment document* in which the term “burning” appears—Ex. 11 at 15—and that document is not only undated, but appears to have come from urology visits in August 2019, *after* Petitioner had already been diagnosed with TM.¹⁴ Such evidence might have warranted more weight had it been shown to be contemporaneous with when Petitioner first complained of what he interpreted (as a layman) to be the after-effects of a painful prostate exam, but it is not—and I do not deem these post-hospitalization records as all that supportive of Petitioner’s arguments about his *initial* symptoms.¹⁵ Otherwise, it remains the case that in addition to neurogenic bladder-like complaints, Petitioner reported other symptoms, like leg weakness, by July 6th (if not the day of vaccination—as alleged in Petitioner’s affidavit), and these could reasonably be attributed to TM itself *independent* of what is alleged to be a prostatitis symptom.

Petitioner fairly contends that his initial symptoms *could* reflect prostatitis rather than TM. But the totality of the evidence better supports the conclusion that Petitioner’s symptoms were likely progressing from the date as vaccination toward what was later ascertained (based on a more complete set of evidence) to be TM—not that he experienced unrelated symptoms coincidentally with his later, more obviously-neurologic symptoms. And the argument that Respondent did not “disprove” prostatitis as a possible explanation is unavailing, since as the party seeking

¹⁴ Petitioner has flagged no other records containing this description of his alleged prostate symptoms—despite ample opportunity to do so—and I have identified no others from my own review of the file.

¹⁵ This is especially so since this set of urology records also repeatedly memorialize urine retention as a concern, suggesting the problem had not abated, and thus allowing for the inference that it remained a byproduct of Petitioner’s TM. *See, e.g.,* Ex. 11 at 13 (progress note from urology visit from August 12, 2019, identifying “retention” as “chief complaint”).

entitlement, Petitioner bears the burden of proof in this case—Respondent is not required to “prove a negative.” Section 13(a)(1). The evidence simply preponderates against Petitioner’s interpretation of these initial symptoms as distinguishable from TM. It does not matter that he *thought* the issues he was experiencing were attributable to his prostate exam. The balance of evidence suggests a neurologic injury was then underway, even if its exact nature remained to be formally identified.

Accordingly, the overall record preponderates in favor of the conclusion that Petitioner’s TM onset likely began the same day as vaccination, or within 24 hours of it at the latest. This determination makes it unlikely that Petitioner’s TM began in a medically-acceptable timeframe, measured from the date of vaccination—even assuming that the Tdap vaccine could cause TM.¹⁶ For any autoimmune process that could conceivably cause TM would take more than a few days before clinical symptoms of TM would manifest.

Petitioner’s causation theory, as presented by Dr. Natarajan, is that (via the oft-referenced mechanism of molecular mimicry) the Tdap vaccine could stimulate the production of autoantibodies that mistakenly attack spinal cord nerve tissues, leading to TM. First Natarajan Rep. at 5. Such a theory involves autoantibodies created during the *adaptive* immune response phase, in reaction to antigenic exposure to the vaccine.¹⁷ As is well understood in the Program, however, the adaptive immune response *lags* the innate, initial response, and takes time to unfold and cause the production of purportedly cross-reactive antibodies.¹⁸ It is not instantaneous—and certainly

¹⁶ This is not a well-founded assumption, although cases exist going the other way as well. *See, e.g., Martinez*, 2022 WL 4884923, at *30 (finding that petitioner did not preponderantly prove that the Tdap vaccine can cause TM); *Palattao v. Sec’y of Health & Hum. Servs.*, No. 13-591V, 2019 WL 989380, at *35-37 (Fed. Cl. Spec. Mstr. Feb. 4, 2019) (denying entitlement in a TM/Tdap case where the facts did not support application of molecular mimicry); *but see Introini v. Sec’y of Health & Hum. Servs.*, No. 20-176V, 2022 WL 16915818, at *24 (Fed. Cl. Spec. Mstr. Oct. 19, 2022) (finding that petitioner proved by a preponderance of the evidence that the Tdap can cause TM via molecular mimicry); *Raymo v. Sec’y of Health & Hum. Servs.*, No. 11-0654V, 2014 WL 1092274, at *21 (Fed. Cl. Spec. Mstr. Feb. 24, 2014) (concluding molecular mimicry explained how the tetanus vaccine can cause TM).

¹⁷ As explained in *Crosby v. Sec’y of Dep’t of Health & Hum. Servs.*, No. 08-799V, 2012 WL 13036266, at *7 n.10 (Fed. Cl. Spec. Mstr. June 20, 2012),

our immune system is comprised of two general types of responses. The first, the innate response, is what all people are born with and makes up the ‘first line of defense’ to antigens. This response is not specific to the particular antigen but is meant to engulf invaders and secrete chemicals to communicate the encounter, which recruits other cells to the site of injury or infection. This innate response also begins the adaptive response. The adaptive response is the system by which our bodies develop a more tailored response to the antigens we encounter. It attempts to remedy any threats that survive past the innate response and creates a memory of sorts to respond to the antigen if it is encountered a subsequent time.

¹⁸ *See e.g., Hock v. Sec’y of Health & Hum. Servs.*, No. 17-168V, 2020 WL 6392770 at *29 (Fed. Cl. Spec. Mstr. Sept. 30, 2020) (noting that a cross-reaction via molecular mimicry, which involves the adaptive response, would not begin within one day of vaccination); *compare Putman v. Sec’y of Health & Hum. Servs.*, No. 19-1921V, 2022 WL 600417 at *24 (Fed. Cl. Spec. Mstr. Jan. 31, 2022) (finding a 26-day period between the vaccine and onset to be a reasonable timeframe for an autoimmune process driven by the adaptive/secondary arm of the immune system).

requires more than a few days. Janeway at 11 (“[a]fter a naïve lymphocyte has been activated, it takes 4 to 5 days before clonal expansion is complete and the lymphocytes have differentiated into effector cells. That is why adaptive immune responses only occur after a delay of several days”).

As a result, a disease-causing process mediated by autoantibodies created in response to a vaccine *could not* result in symptoms the same day as vaccination (or likely even the day after). *See, e.g., Martinez v. Sec’y of Health & Hum. Servs.*, No. 16-738V, 2022 WL 4884923, at *26 (Fed. Cl. Spec. Mstr. Sept. 9, 2022), *mot. for review den’d*, 165 Fed. Cl. 76 (2023) (finding onset of TM 24 hours post-vaccination to be too close in time to have been caused by the Tdap vaccine); *Mosley v. Sec’y of Health & Human Servs.*, No. 08-724V, 2015 WL 2354316, at *19 (Fed. Cl. Spec. Mstr. Apr. 27, 2015) (“onset of TM one day after tetanus vaccine is too soon to support vaccine causation”); *Jagoe v. Sec’y of Health & Human Servs.*, No. 08-678V, 2012 WL 13036265, at *28 (Fed. Cl. Spec. Mstr. Aug. 3, 2012) (determining that TM symptoms occurring within 24 hours of vaccination were not a medically appropriate timeframe for vaccine causation). Onset occurring within one day of the vaccination points to an adaptive immune process that likely was already underway, since it would take several days from the inciting event for the autoantibodies driving TM to generate. *Martinez*, 2022 WL 4884923 at *27.

Dr. Natarajan did not otherwise establish how a 24-hour onset period would be possible in this case. Although he briefly mentions that the onset of TM can occur within hours following a vaccine, he does not elaborate on this point, or provide sufficient independent evidence to support it. First Natarajan Rep. at 4. Furthermore, he is unwavering in his contention that the onset of Petitioner’s TM occurred a few days after Petitioner’s July 3rd vaccination (although he fluctuates between an onset date of July 6th vs. July 8th). *Compare* First Natarajan Rep. at 4 (“On July 6, 2019, [Petitioner] reported what I consider actual symptoms of myelitis for the first time”) *with* Second Natarajan Rep. at 2 (“The onset of [Petitioner’s] symptoms of Transverse Myelitis was July 8-9”).

Again—Petitioner’s arguments about prostatitis are reasonable, and they have some objective support. There is record evidence supporting prostatitis as an explanation for his initial symptoms (despite my ultimate conclusion that the record preponderates against that same conclusion—and I reach this determination after *a thorough review and balancing of the evidence*). Petitioner may well have reasonably thought his physical exam explained his immediate symptoms, and he so informed treaters. I also note that it is always possible that *some* symptoms a claimant experiences in a post-vaccination period could prove to be independent of a subsequent vaccine injury.

But as I have discussed above—and as is supported clearly by independent items of medical literature—TM can often involve some initial urologic symptoms that might easily be confused as reflecting something else. Here, the record establishes that Petitioner’s overall course—from the July 3rd vaccination to his mid-July hospitalization—progressed, with more and more manifestations of obviously-neurologic symptoms until treaters arrived at TM as the

etiologic explanation (and after lab work and imaging results corroborated the diagnosis). It is more likely than not that his initial symptoms were not prostatitis, and thus his TM began too close in time to vaccination to deem the vaccination causal. Petitioner's personal *belief* that his initial symptoms reflected prostatitis is not enough to overcome the substantial evidence to the contrary. *Markovich*, 477 F.3d at 1357.

CONCLUSION

Vaccine Act claimants must carry their burden of proof to be entitled to damages. Because Petitioner cannot show by preponderant evidence that his TM began in a medically-acceptable timeframe, I deny entitlement.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.¹⁹

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

¹⁹ Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.